Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 15, 1998 list were made in August, 1998

New Approvals

ANADA Number: 200-180

Pioneer Product:	055-030
Trade Name:	Ampicillin Trihydrate
Ingredients:	Ampicillin trihydrate
Sponsor:	G. C. Hanford Mfg. Co.
Approval Date:	04/24/98
Status:	Prescription only
Route:	Subcutaneous, intramuscular
Species:	Canine, feline, bovine
Drug Form:	Powder
Concentration:	10g/100mL vial, 25g/250mL vial
Indications:	For the treatment of respiratory tract, urinary tract, gastrointestinal infections and skin, soft-tissue and post-surgical infection in dogs and cats. Respiratory tract infections in cattle and calves including non-ruminating (veal calves).
Tolerance:	21CFR 556.40: A tolerance of 0.01 ppm is established for negligible residues of ampicillin in the uncooked edible tissues of cattle and in milk.
Withdrawal:	6 days for the edible tissues of cattle and 48 hours for milk.

21CFR 522.90 and 556.40

ANADA Number: 200-219

Pioneer Product:	140-841
Trade Name:	Phoenectin™ Pour-On for Cattle
Ingredients:	Ivermectin
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	07/06/98
Status:	Over-the-counter
Route:	Topical
Species:	Bovine
Drug Form:	Liquid (solution)
Concentration:	5 mg/mL
Indications:	For the treatment and control of the following parasites: gastrointestinal roundworms (*Ostertagia ostertagi*, adult and fourth stage larvae including inhibited stage; *Haemonchus placei*, adults and fourth stage larvae; *Trichostrongylus axei*, adults and fourth stage larvae; *T. colubriformis*, adults and fourth stage larvae; *Cooperia spp.*, adults and fourth stage larvae; *Strongyloides papillosus*, adults; *Oesophagostomum radiatum*, adults and fourth stage larvae; *O. venulosum*, adults only; *Trichuris spp.*, adults: lungworms (*Dictyocaulus viviparus*, adults and fourth stage larvae); cattle grubs (*Hypoderma bovis, H. lineatum*, parasitic stages): mites (*Sarcoptes scabei var. bovis, Chorioptes bovis*): lice (*Linognathus vituli, Haematopinus eurysternus, Damalina bovis, Solenoptes capillatus*): and horn flies (*Haematobia irritans)*.
Tolerance:	21CFR 556.344(a). A tolerance is established for 22,23-dihydroavermectin B_1a in liver as 100 ppb.
Withdrawal:	48 days

21CFR 524.1193

ANADA Number: 200-254

Pioneer Product:	106-772
Trade Name:	Iron Dextran Injection
Ingredients:	Iron hydrogenated dextran
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	07/14/98
Status:	Over-the-counter
Route:	Intramuscular
Species:	Porcine
Drug Form:	Liquid (solution)
Concentration:	100 mg/mL of elemental iron as iron dextran complex
Indications:	For the prevention and treatment of iron deficiency anemia in baby pigs.
Tolerance:	Not established.
Withdrawal:	Not established.

21CFR 522.1183

ANADA Number: 200-248

Pioneer Product:	100-237
Trade Name:	Pyrantel Pamoate Suspension
Ingredients:	Pyrantel pamoate
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	07/16/98
Status:	Over-the-counter
Route:	Oral
Species:	Canine
Drug Form:	Liquid (suspension)
Concentration:	2.27 and 4.54 mg/mL pyrantel base as pyrantel pamoate
Indications:	To prevent reinfection of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping. For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies.

21CFR 520.2043

NADA Number: 046-718 (Liquid MGA) & 046-719 (Dry MGA)

Trade Name:	MGA®, Terramycin®
Ingredients:	Melengestrol acetate (MGA), Oxytetracycline (OTC)
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	05/06/98
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (cattle, heifers fed in confinement for slaughter)
Drug Form:	Type A medicated article to make dry combination Type C medicated feed
Concentration:	Melengestrol acetate 0.0000276-0.00022 % (25-200 g/ton); Oxytetracycline 75-300 g/ton for Type C medicated feed
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and reduction of liver condemnation due to liver abscesses in heifers fed in confinement for slaughter.
Tolerance:	21CFR 556.380:Melengestrol acetate: A tolerance of 25 ppb is established for residues of the parent compound in fat. 21CFR 556.500: Oxytetracycline: 2.0 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal:	Zero days

This NADA provides for the combined use of two approved Type A medicated articles (MGA and OTC) in the manufacture of Type C medicated feeds for heifers fed in confinement for slaughter.

21CFR 558.342 and 558.450

NADA Number: 140-973

Trade Name:	Ventipulmin® Syrup
Ingredients:	Clenbuterol hydrochloride
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	05/11/98
Status:	Prescription only
Route:	Oral
Species:	Equine
Drug Form:	Liquid (syrup)
Concentration:	72.5 mcg/mL
Indications:	For use in the treatment of horses with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).
Exclusivity:	5 years

21CFR 520.452

NADA Number: 141-044

Trade Name:	Ovuplant™
Ingredients:	Deslorelin acetate
Sponsor:	Peptech Animal Health Pty, Limited
Approval Date:	06/18/98
Status:	Prescription only
Route:	Subcutaneous (implantation)
Species:	Equine
Drug Form:	Implant
Concentration:	2.1 mg/implant
Indications:	For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 mm in diameter.
Patent Number:	5,545,408 Expiration Date: 08/13/2013
Exclusivity:	5 years

21CFR 522.533 and 510.600

NADA Number: 141-107

Trade Name:	BAPTEN® For Injection
Ingredients:	β-aminopropionitrile fumarate
Sponsor:	Alaco, Inc.
Approval Date:	06/10/98
Status:	Prescription only
Route:	Intralesionally
Species:	Equine
Drug Form:	Powder (lyophilized) for reconstitution
Concentration:	0.7 mg/mL
Indications:	For the treatment of tendinitis of the superficial digital flexor tendon (SDFT) in the adult horse where there is sonographic evidence of fiber tearing.
Patent number:	4,485,088 Expiration Date: 11/27/2001
Exclusivity:	5 years

21CFR 522.84 and 510.600

Supplemental Approvals

NADA Number: 141-063

Trade Name:	Nuflor® Injectable Solution
Ingredients:	Florfenicol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	06/04/98
Status:	Prescription only
Route:	Subcutaneous
Species:	Bovine
Drug Form:	Liquid (solution)
Concentration:	300 mg/mL
Indications:	For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica, Pasteurella multocida,* and *Haemophilus somnus.*
Tolerance:	21CFR 556.283: An acceptable daily intake (ADI) for total residues is 10 micrograms/kilogram of body weight per day. A tolerance of 3.7 ppm for florfenicol amine (the marker residue) has been established in cattle liver (the target tissue). A tolerance of 0.3 ppm for florfenicol amine in cattle muscle is established.
Withdrawal:	38 days
Exclusivity:	3 years

This supplemental application provides for the addition of a new route, dose, and a longer withdrawal time.

21CFR 522.955 and 556.283

NADA Number: 141-084

Trade Name:	Sentinel™ Flavor Tabs®
Ingredients:	Milbemycin oxime, lufenuron
Sponsor:	Novartis Animal Health US, Inc.
Approval Date:	06/17/98
Status:	Prescription only
Route:	Oral
Species:	Canine
Drug Form:	Tablet
Concentration:	Three tablet sizes: 5.75 mg milbemycin oxime/ 115 mg lufenuron, 11.5 mg mibemycin oxime/ 230 mg lufenuron, and 23 mg milbemycin oxime/ 460 mg lufenuron per tablet.
Indications:	For use in dogs and puppies four weeks of age and older and eleven pounds body weight or greater, for the prevention of heartworm disease caused by *Dirofilaria immitis*, for the prevention and control of flea populations, the control of adult *Ancylostoma caninum* (hookworm), and the removal and control of adult *Toxocara canis, Toxascaris leonina* (roundworm) and *Trichuris vulpis* (whipworm) infections.
Patent Number:	4,547,520 Expiration Date: 06/14/2004
Exclusivity:	3 years

This supplemental application provides for addition of a flavored tablet formulation to replace the swallow tablets for dogs not less than 11 pounds. The swallow tablet will remain for dogs between 2-10 pounds.

21CFR 520.1446

NADA Number: 140-915

Trade Name:	SAFEHEART™
Ingredients:	Milbemycin oxime
Sponsor:	Novartis Animal Health US, Inc.
Approval Date:	06/04/98
Status:	Prescription only
Route:	Oral
Species:	Canine
Drug Form:	Tablet
Concentration:	Two tablet sizes: 2.3 mg and 5.75 mg per tablet
Indications:	For the prevention of heartworm disease caused by *Dirofilaria immitis* in dogs and puppies four weeks of age or greater and 2 pounds of body weight or greater.
Exclusivity:	3 years

This supplemental application provides for adding a lower dosage for use in the prevention of heartworm disease in dogs and puppies and a new tradename. The original conditions of approval for Interceptor® under NADA 140-915 remain unchanged.

21CFR 520.1445

NADA Number: 141-034

Trade Name:	GAINPRO®
Ingredients:	Bambermycins
Sponsor:	Hoechst Roussel Vet
Approval Date:	06/29/98
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (cattle fed in confinement for slaughter (feedlot cattle); pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)).
Drug Form:	Type A medicated article
Concentration:	10g bambermycins/lb in the Type A medicated article
Indications:	For increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter (feedlot cattle) and for increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder cattle and dairy and beef replacement heifers).
Tolerance:	Not established.
Withdrawal:	Not established.
Exclusivity:	3 years

This supplemental application provides for the removal of the caution statement "Not for Use in Animals Intended for Breeding" in feedlot and pasture cattle, and the addition of dairy and beef replacement heifers to the indications for use in pasture cattle.

21CFR 558.95

NADA Number: 141-059

Trade Name:	BMD® 10, 25, 30, 40, 50, 60 or 75 and CTC® 50, 65 or 70 Type A Medicated Articles
Ingredients:	Bacitracin methylene disalicylate, chlortetracycline
Sponsor:	Alpharma, Inc.
Approval Date:	06/24/98
Status:	Over-the-counter
Route:	Oral
Species:	Porcine (feeder pigs)
Drug Form:	Type A medicated articles to make Type B medicated feeds
Concentration:	Bacitracin methylene disalicylate 10, 25, 30, 40, 50, 60, or 75 grams of bacitracin activity per pound; chlortetracycline 50, 65, 70 g/lb.
Indications:	Bacitracin methylene disalicylate Type A medicated article for increased rate of weight gain and improved efficiency. Chlortetracycline Type A medicated article for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.
Tolerance:	21CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of swine. 21CFR 556.150: Chlortetracycline: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

This supplemental application provides for using currently approved, single ingredient, Type A medicated articles in making combination drug Type B medicated swine feeds containing bacitracin methylene disalicylate and chlortetracycline.

21CFR 558.76

NADA Number: 008-622

Trade Name:	Terramycin-343® Soluble Powder
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Pfizer, Inc.
Approval Date:	06/19/98

This supplemental application provides for added package sizes (2.25 pond jars and 4.5 pound pails) to the existing approval.

21CFR 520.1660

ANADA Number: 200-118

Pioneer Product:	011-315
Trade Name:	Neomycin Sulfate Oral Solution
Ingredients:	Neomycin sulfate
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	07/14/98
Status:	Over-the-counter
Route:	Oral
Species:	Porcine, caprine, bovine (excluding veal calves), ovine
Drug Form:	Liquid (solution)
Concentration:	200 mg/mL equivalent to 140 mg/mL neomycin base
Indications:	For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.
Tolerance:	21CFR 556.430: A tolerance of 7.2 ppm is established for residues of parent neomycin (marker residue) in uncooked edible kidney (target tissue), 7.2ppm in fat, 3.6 ppm in liver, 1.2 ppm in muscle of cattle, swine, sheep, and goats. A tolerance of 0.15 ppm is established for neomycin in milk.
Withdrawal:	1 day in cattle; 2 days in sheep; 3 days for swine and goats.

This supplemental application provides for the revision of the withdrawal times prior to slaughter to be identical to the pioneer product.

21CFR 520.1485

NADA Number: 009-576

Trade Name:	Synovex® C and Synovex® S
Ingredients:	Estradiol benzoate and Progesterone
Sponsor:	Fort Dodge Animal Health
Approval Date:	07/14/98
Status:	Over-the-counter
Route:	Subcutaneous (implant)
Species:	Bovine
Drug Form:	Implant (ear)
Concentration:	2.5 mg estradiol benzoate and 25 mg progesterone per pellet. Synovex® C is made up of four pellets. Synovex® S is made up of eight pellets.
Indications:	Synovex® C is recommended for use in suckling beef calves up to approximately 400 pounds of body weight. It is also recommended for improvement in rate of weight gain in steers weighing greater than 400 pounds and fed in confinement for slaughter when used as part of a re-implant program in which an initial Synovex® C implant is followed at approximately 70 days by Synovex® S. Synovex® S is indicated for increased rate of weight gain and improved feed efficiency. For additional improvement in rate of weight gain in steers fed in confinement for slaughter, Synovex® S may be used as part of a re-implant program where an initial Synovex® C or Synovex® S implant is followed by Synovex® S at approximately 70 days.
Tolerance:	21CFR 556.240: Estradiol and related esters: In the uncooked edible tissues of heifers, steers and calves: 120 ppt for muscle, 480 ppt for fat, 360 ppt for kidney, and 240 ppt for liver. 21CFR 556.540: Progesterone: In the uncooked edible tissues of steers and calves: 3 ppb for muscle, 12 ppb for fat, 9 ppb for kidney, and 6 ppb for liver.

This supplemental application provides for the implantation of Synovex® C in steers fed in confinement for slaughter when used as part of a re-implant program where Synovex® S is implanted at approximately day 70 after the initial implantation of Synovex® C.

21CFR 522.1940

New Sponsor

Peptech Animal Health Pty, Limited
35-41 Waterloo Rd.
North Ryde, New South Wales 2113
Australia
Drug labeler code: 064288

Alaco, Inc.
1500 North Wilmot Rd., suite 290-C
Tuscon, AZ 85712
Drug labeler code: 064146

Change of Sponsor

NADA Number: 135-773

From: Ohmeda Pharmaceutical Products Division
To: Baxter Pharmaceutical Products, Inc.
110 Allen Rd., P.O. Box 804
Liberty Corner, NJ 07938
Drug labeler code: 010019

Change of Sponsor Name

From: Rhone-Poulenc Chemicals, Ltd.
To: Rhodia Limited
Drug labeler code: 059258